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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,334	06/22/2000	Thomas Graf	2565/74	7641
26646	7590	04/07/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,334

Applicant(s)

GRAF ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/04 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 7, 12, and 13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bene (5,744,031). Bene discloses a dialysis system comprising a dialyzer (1) divided by a semipermeable membrane (4) into a blood chamber (2) and a dialysis chamber (3). The blood chamber has an inlet connected to an arterial blood line (5) and an outlet connected to a venous blood line (7). Since the claim is open-ended (i.e. "comprising"), the venous line is seen to be connected to the blood outlet regardless of the intervening bubble trap. Further, the claim does not require that the venous line be "directly connected" to the outlet. Therefore this limitation is met. The dialysis chamber has an inlet connected to a dialysis fluid inlet line (13) and an outlet connected to a dialysis fluid outlet line (29). A blood pump (6) is connected to the arterial, a first dialysis fluid pump (15) is connected to the dialysis inlet line and a second dialysis fluid pump (22) is connected to the dialysis fluid outlet line. Bene also discloses flow meters (24/25) measure the inflow and outflow rates of the dialysis fluid. Bene also discloses that the computing and control unit (26) can calculate the dialysance of the apparatus during the treatment session based on blood flow rate and/or dialysis liquid flow rate values sent to the control unit (see figure 1 & col. 4, line 33-col. 6, line 51). With respect to claim 7, since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it is the position of the examiner that the computing and control unit of Bene is equivalent to that of a computer.

As stated in the previous office action, it is the position of the examiner that the disclosed computing and control unit 26 of Bene functions as a computer. This unit

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controls the system based on signals measured throughout the entire system according to parameters that it calculates, such as blood flow rate, and parameters of the performance of the system, such as dialysance, and according to the data that is supplied to the computing or control unit 26 prior to the start of treatment, such as a desired blood flow rate of the blood or the dialysis fluid (col. 5, line 65-col. 6, line 25). The computing and control unit receives, manipulates the data, and calculates dialysance based on measurements made, one being blood flow. Since by definition a computer "is a device that computes data via mathematical operations, the computing and control unit of Bene is equivalent to applicant's claimed computer. Bene also gives an example wherein the computing or control unit 26 is capable of modifying the programmed treatment session based on the calculations it generates (col. 7, lines 11-35). Since the computing or control unit 26 of Bene independently calculates values based upon comparisons of measured parameters of the system, wherein one measurement is blood flow, with data programmed into the unit at the beginning of treatment, it is seen to be a computer. Therefore, it is the position of the examiner that the computing or control unit 26 of Bene is disclosed a computer unit that can determining clearance or dialysance based upon at least one of the clearance and dialysance and at least one of a blood flow rate and dialysis fluid flow rate, with at least one of a predetermined blood flow rate, predetermined dialysis fluid flow rate, and a predetermined ultrafiltration rate.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 10, and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bene ('031). Bene discloses the invention substantially as claimed, see rejection supra. Bene, however, fails to disclose specifically that the computer calculates a diffusive component D_1 , effective blood flow Q_e (claim 9), the diffusive dialysance $D(Q_d(t))$ for any flow rate $Q_d(t)$ (claim 10), and the sum of the diffusive and convective dialysance $k(Q_d(t), Q_e, Of(t))$ or the clearance from the diffusive dialysance $D(Q_d(t), Q_e(t))$ according to their respective equations set forth in their respective claims. However, since the computing and control unit of Bene computes values using

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formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it clearly uses programmable software to perform the mathematical calculations. Therefore, the computing and control unit of Bene is clearly capable of being programmed with the required equations such that the control unit can calculate the diffusive component $D1$, effective blood flow Q_e (claim 9), the diffusive dialysance $D(Q_d(t))$ for any flow rate $Q_d(t)$ (claim 10), and the sum of the diffusive and convective dialysance $k(Q_d(t), Q_e, Of(t))$ or the clearance from the diffusive dialysance $D(Q_d(t), Q_e(t))$. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computing and control unit of Bene to store the desired equations to calculate diffusive component $D1$, effective blood flow Q_e (claim 9), the diffusive dialysance $D(Q_d(t))$ for any flow rate $Q_d(t)$ (claim 10), and the sum of the diffusive and convective dialysance $k(Q_d(t), Q_e, Of(t))$ or the clearance from the diffusive dialysance $D(Q_d(t), Q_e(t))$, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

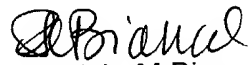
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 3rd, 2004


Patricia M Bianco
Primary Examiner
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